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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,681	02/08/2004	Michael Scott Ehrlich	C1159.70000US01	9429

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600 Atlantic Avenue  
Boston, MA 02210

EXAMINER
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CLOW, LORI A

ART UNIT	PAPER NUMBER
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1631

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05/02/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/774,681

Applicant(s)

EHRLICH, MICHAEL SCOTT

Examiner

Lori A. Clow, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5, 19 and 25-38 is/are pending in the application.
- 4a) Of the above claim(s) 1-5, 26, 37 and 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19, 25 and 27-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's election without traverse of Group II, claims 19 and 25-36 in the reply filed on 5 March 2007 is acknowledged. Claims 6-18 and 20-24 are cancelled. Claims 1-5, 26, 37 and 38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 5 March 2007.

Claims 19, 25, and 27-36 are examined herein.

#### **Priority**

Priority to US Provisional Application 60/527,205, filed 4 December 2003 is acknowledged.

#### **Drawings**

The drawings filed 8 February 2004 are accepted.

#### **Claim Rejections - 35 USC § 112-2<sup>nd</sup> paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19, 25, and 27-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 19 recites, “determining a cell distribution profile for a plurality of the intact cells using a procedure that sorts the intact cells based on an amount of a physiological variable in each of the sorted cells”. It is unclear what distribution is being measured. Is it a distribution of different cell types in a sample or a distribution of cells with a certain cellular marker. The claimed method step is directed to obtaining a profile, however, the parameters of the profile are unclear. Clarification is requested.

Claim 25 recites, “ a method of recovering the blood glucose level history of a patient”. It is unclear what is intended by “recovering”. Has the blood glucose level in the method been previously lost? Clarification is requested.

Claim 25 recites, “obtaining a cell distribution profile by sorting a plurality of the intact cells based on the amount of glycated hemoglobin...and determining the patient’s glucose level history based on the cell distribution profile”. It is unclear as to what about the cell distribution profile will determine a patient’s blood glucose history. Further, what distribution is being evaluated? The ratio of non-glycated to glycated red blood cells, for example? Clarification is requested.

Claim 26 recites, “wherein the patient’s blood glucose level history is obtained by comparing the patient’s cell distribution profile to one or more reference profiles”. It is unclear as to what encompasses a “reference profile”. Is it a reference profile of blood glucose levels or some other reference profile? Clarification is requested.

Claim 27 recites, “wherein the patient’s blood glucose level history is obtained using an algorithm”. It is unclear for what the algorithm is used to obtain a glucose history. Is the algorithm for assessing glycation events or some other purpose? Clarification is requested.

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Claim 33 recites, “the method of claim 25 comprising the additional step of determining whether the patient has Type I, Type II, or gestational diabetes”. It is unclear what parameters are to be considered in order to determine whether a patient has Type I, Type II, or gestational diabetes? If the distribution is within a certain range, for instance, does that indicate diabetes?

Clarification is requested.

Claim 34 recites, “the additional step of determining a treatment regime for the patient”. It is unclear what the parameters of a treatment regime are based. Clarification is requested.

### **Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claim 19 is rejected under 35 U.S.C. 102(e) as being anticipated by US 6,540,895 (Spence et al.).

The instant claims are drawn to a method of obtaining a cell distribution profile of a patient comprising obtaining a biological sample and determining a cell distribution based upon a physiological variable of the sorted cells.

6,540,895 (‘895) teaches a device and method for sorting cells based upon a desired characteristic (abstract). For example, labeled cells are sorted depending on the level of reporter

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in the cells. The method is useful for sorting blood cells and can be used to sort any cell on the basis of whether or not it expresses a detectable protein (column 4, line 54-64).

2. Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by 6,784,981 (Roche et al.).

6,784,981 ('981) teaches flow cytometric methods and systems for analysis of biological samples, particularly blood sample (abstract). The system can determine a distribution of white blood cells and other cells in a whole blood sample. The system is capable measuring hemoglobin in the sample (physiological variable) (column 30).

### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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Claims 25 and 27-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over 6,540,895 (Spence et al.) in view of 4,835,097 (Saunders).

6,540,895 ('895) teaches a device and method for sorting cells based upon a desired characteristic (abstract). For example, labeled cells are sorted depending on the level of reporter in the cells. The method is useful for sorting blood cells and can be used to sort any cell on the basis of whether or not it expresses a detectable protein (column 4, line 54-64).

'895 does not teach the method as applied to diabetes using glycated hemoglobin. However, '097 teaches the measurement of glycolated hemoglobin for assessing the physical condition of a diabetic patient over time (column 1). Further, '097 teaches the monitoring of glucose using the hemoglobin levels over time (column 4). While '097 does not specifically teach an algorithm to obtain a blood glucose level, '097 does teach incremental interval evaluation (column 9). It would have been prima facie obvious to one of skill in the art at the time of the invention to have assessed levels using an algorithm to generate intervals for assessment of patient glucose. One would have been motivated to do so because glucose history facilitation using a computer is taught at column 11.

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have used the cell sorter of '895 in the diabetes assessment of '097. One would have been motivated to do so because '895 teaches that the cell sorter can be used to sort cells for any characteristic, in particular it is most useful to separate blood cells (column 4).

No claims are allowed.

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**Inquiries**

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

April 29, 2007

Lori A. Clow, Ph.D.

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*Lori A. Clow*  
*Patent Examiner*